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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,491	09/05/2003	Dagmar Beyerlein	5618.P3653	8370

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04/01/2009

EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

04/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/656,491

Applicant(s)

BEYERLEIN, DAGMAR

Examiner

CATHERINE N. WITCZAK

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date 3/11/2009
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 2, 3, 6, and 8 rejected under 35 U.S.C. 102(b) as being anticipated by Sicurelli et al (US 6,162,202).

Sicurelli et al disclose in Figure 4 a system comprising a needle with a first and second opening (17c), and a fluid pressure sensor (550) configured to measure a first, second, and third pressure change as therapeutic agent is injected.

2. Claims 1, 2, 3, 6, and 8 rejected under 35 U.S.C. 102(b) as being anticipated by Galindo (US 4,411,657).

Galindo discloses in Figure 1 a system comprising a needle with a first and second opening (18), and a fluid pressure sensor (column 2, lines 40-50) configured to measure a first, second, and third pressure change as therapeutic agent is injected.

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3. Claims 1, 2, 3, 6, and 8 rejected under 35 U.S.C. 102(e) as being anticipated by Flaherty et al (US 6,283,951).

Flaherty et al disclose in Figure 5c a system comprising a needle (62) with a first and second openings (75), and a fluid pressure sensor (column 17, lines 42-52) configured to measure a first, second, and third pressure change as therapeutic agent is injected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5, 7, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sicurelli et al OR Galindo OR Flaherty et al in view of Sicurelli et al OR Galindo OR Flaherty et al.

Sicurelli et al OR Galindo OR Flaherty et al discloses the claimed invention except for expressly disclosing the size of the aperture, distance of the aperture from the end of the needle, and outer/inner diameter of the syringe. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to change the are, distance, and diameters because Applicant has not disclosed that these values provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have been able to change these values in order to control the amount of flow and location of outflow as desired. Therefore, it would have been an obvious matter of design choice to modify Sicurelli et al OR Galindo OR Flaherty et al to obtain the invention as specified in claims 5, 7, 9, and 10.

5. Claims 11, 12, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sicurelli et al OR Galindo OR Flaherty et al as modified by Sakariassen (US 5,662,107).

Sicurelli et al OR Galindo OR Flaherty et al disclose the claimed invention except for a computer processor coupled to the assembly. Sakariassen discloses in Figure 1 that it is known to use a computer processor coupled to a fluid pressure assembly. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Sicurelli et al OR Galindo OR Flaherty et al with a computer processor as taught by Sakariassen, since such a modification would provide more accurate, more sophisticated, easier to display feedback than a manual pressure indicator.

Response to Arguments

Applicant's arguments filed 12/11/2008 have been fully considered but they are not persuasive. Applicant argues that the prior art (Sicurelli, Galindo and Flaherty) does not disclose a measurement assembly configured to measure a third pressure that is a second pressure change when the needle penetrates tissue and the aperture of a second opening becomes occluded. Examiner disagrees. Each of the prior art references disclose a needle with multiple apertures and a pressure sensing device. Even though the prior art may not explicitly disclose using the device to measure a third pressure that is a second pressure change when the needle penetrates tissues and the aperture of the second opening becomes occluded, since each of the references discloses the needle structure claimed and a pressure measuring assembly connected to the needle, it would be inherent that the devices could be employed in various situations to determine pressure changes, including situations such as ones in which the pressure changes resulting from an aperture becoming occluded.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Catherine N Witczak/

Examiner, Art Unit 3767

/Kevin C. Simons/

Supervisory Patent Examiner, Art Unit 3767